REMARKS

Claims 1-6, 10-22, 24-26, 28-29 and 34-35 are pending in the application. Claims 30, 32 and 33 correspond to unelected species and are withdrawn. Claim 23 was withdrawn from further consideration by the Examiner in the Office Action mailed 12 November 2008. Claims 7-9, 27 and 31 were cancelled in a previous response (February 12, 2009). Claims 34 and 35 were added in the same response on February 12, 2009.

Applicant notes with appreciation the withdrawal of the finality of the previous office action.

35 USC 103(a) Rejections over Fixel et al (US 3,990,116) in view of Persson et al (US 5,011,497)

Claims 1-5, 8-12, 14-22, 31, 34 and 35 stand rejected under 35 USC 103(a) as being obvious over Fixel in view of Persson.

Applicant notes that claims 8, 9, and 31 were cancelled in the response filed in February 2009. Accordingly, the § 103 objection as it applies to these claims is believed to be moot.

Examiner has acknowledged that Fixel fails to disclose that the flexible member is smaller than the bore and that is it free to float and move. However, the Examiner contends that supplying those features would be obvious from Persson.

Applicant notes that claim 1 (and the dependent claims thereon) requires at least the following two features that are not disclosed in Fixel:

1) the cavity formed by the bores in the first and second components is longer than the flexible component *so that the flexible component can move axially within the cavity*; and

2) the flexible component is free to move laterally and rotationally within the cavity.

Persson discloses a joint prosthesis with a pair of tubular screws 17 into which are inserted pins 11 that are connected by an elastic joint 10 formed by injection moulding an elastomeric material around the flanges of the ends of the pins (see column 1 line 66-70). The elastic joint 10 (contrast figs 1 and 2) also has a particular orientation to allow up and down flexion of the finger. The elastic joint 10 is not received within the cavity. Instead, the pins are pushed into the bores of the tubular screws until the flanges (which are too large to enter the bores of the screws) abut against the outer flanges of the screws (see Fig 3). As taught in column 2 line 26-27 the pins are held in the bores by the compression of the elastic joint 10 between them when the prosthesis is in place.

Column 2, lines 29-30 of Persson state that

> "The pins may be locked in the screws after mounting. *Since there is no movement between the pins and the screws* when the prosthesis is being used, the wear of the prosthesis is kept to a minimum, which means that the life will be long and the risk for infections or irritations due to particles from the prosthesis penetrating into the tissues of the body is eliminated practically completely. (emphasis added)

This passage in Persson clearly teaches one of *ordinary* skill in the art that movement of the pins relative to the tubular screws is completely undesirable after the initial mounting stage. Later passages also teach that anti-rotation devices (such as matching hexagonal cross sections for the pins and bores) should be used to prevent the pins from rotating in the bores of the screws as this would result in rotation of the elastic joint 10 out of the correct plane of movement.

These are not subtle suggestions that are hidden within Persson's subtext. They are very explicit repeated warnings that *any* post installation movement between the pins and the screws is undesirable and that relative rotation is particularly undesirable. The consequences for relative movement are also clearly spelled out in Persson, *i.e.*, infection and irritation resulting from particles being generated by the relative movement of the pins and screws after the prosthesis is implanted in the patient's body. Therefore, the person of *ordinary* skill in the art would conclude from these teachings of Persson that while rotation of the pins and

screws is useful while installing the joint in the patient's body, after the prosthesis is in use, steps should be taken to ensure that no movement of the pins and the screws occurs, and certainly no rotation, even if this involves expensive design options like the anti-rotation devices recommended at column 2, lines 44-8.

The repeated and imperative teaching in Persson of fixing the screws and the pins against movement in the installed device is completely contrary to the present claims. An ordinarily skilled person looking to improve the Fixel device and reading Persson would not adapt the Fixel device to make the Fixel stack of leaf springs 17 movable within the cavities 15 and 16. In fact, if any modification were to be contemplated based on combinations of Fixel and Person, it would be that further steps to *prevent* relative movement of the spring stack 17 and the cavities 15 and 16 should be taken, for example, by locking them in place, and/or incorporating anti-rotating splines or hexagonal cross sections as recommended by Persson. Thus, a person of *ordinary* skill tempted to combine Fixel and Persson would actually be led directly away from the combination of features now claimed.

Additionally, Applicant submits that any modification of Fixel to enable the free movement of the spring stack 17 within the cavities 15 and 16 would not work, based on Persson or any other document. In Fixel, the rectangular spring stacks 17 fit snugly within the cavities 15, 16 in a close fit as shown in Figs. 1, 2 and 5. Note that the dotted lines in Fig. 5 show the cavity clearly with a matching cross section with the spring stack 17 filling the whole of the cavity so that relative movement is restrained. This is also apparent from Figs. 1 and 2. It is clear from the discussion at column 3, lines 15-18 that the thickness of the spring stack 17 is limited by the dimensions of the joint, and it would make no sense to make the spring stack 17 narrower than the cavity. This is not accidental. It is an important design feature of Fixel, which, if ignored, would result in significant disadvantages. In the Fixel design, the spring stack 17 transfers the forces between the two members 11 and 12 during movement of the finger. With the spring stack 17 filling the cavities 15, 16 and held therein against movement, the forces are transmitted along the embedded length of the spring stack 17, so that a large surface area on the inside surface of the cavities of the members 11 and 12 bears the force. Also, the leaf springs are held tightly together and against movement relative to one another. The result is that reaction forces are evenly spread along the inside

of the side walls of the cavities 15,16, and no single part of the spring stack 17 or the side walls of the cavities bears excessive amounts of force. Also, the leaf springs do not move relative to one another and behave as a single unitary spring.

If the cavities 15 and 16 were to be enlarged so that the springs in the stack 17 could move axially, laterally and rotationally within the cavity, then when forces were transmitted across the spring stack 17, the spring stack 17 would be moved diagonally across the cavity 15, contacting the cavity side walls only at diagonally opposite ends of the cavity 15 while the force was applied. This would place excessive pressure on the outer edge of the cavity, and on the diagonally opposite inner corner. When the direction of force is reversed, the spring stack 17 would move to the opposite corners. The repeated impacts of the spring stack 17 against the one edge and then the other opposite edge would cause fragmentation of particles from the inner surface of the cavities. Also, the higher loads on these edges that would result from the same force being applied to a tiny surface area on the very outer edges of the cavities would increase the generation of particles. This would be a highly undesirable result of the modification, as the particles would be free to migrate into the patient's tissues, causing infection, irritation, adverse immunological reactions to the particles, and other difficulties, which is exactly what Persson cautions against (see column 2 line 33-35).

As well as degrading the walls of the cavities, increasing the spacing between the cavities and the spring stacks 17 would lead to degradation of the springs, as they would themselves become disordered and damaged, generating additional particles from the spring materials and increasing the scraping action of the disordered springs against the cavity walls. As additional wear particles accumulate between the flat surfaces between the leaf springs, the generation of wear particles would increase exponentially, as the wear particles would further abrade large surface areas of the leaf spring surfaces as the leaf springs slide relative to one another within the stack (a well-known effect known in orthopaedics as third-body wear).

Any person of *ordinary* skill considering these design issues at the priority date of the present application (2002) would be acutely aware of the need to minimize the wear of implanted objects in order to minimize wear particle generation from the implanted joint.

The generation of wear particles from implanted replacement joints and the resultant immune response by the body of the patient (known in the art as osteolysis) is a ubiquitous problem known to all persons skilled in the art of designing of orthopaedic implants. According to the attached extract from a standard textbook in the field, Miller, M. (2004), *Review of Orthopaedics*, 4th Ed., Philadelphia: Saunders, osteolysis is "at this time (*i.e.*, 2004) remains the most vexing problem in total joint arthroplasty [*i.e.*, replacement]", *p.* 278. The Examiner is requested to take official notice of this publication, and to note that the author's use of the word "remains" clearly means that osteolysis was a continuing problem. From *Review of Orthopaedics*, it is clear that the person of *ordinary* skill in the art would realize that the increased freedom of movement of the spring stack 17 in Fixel would increase the generation of wear particles as explained above, and therefore would not attempt to modify Fixel on the basis of Persson or any other document to increase the range of movement of the Fixel springs within the cavities 15 and 16. In particular a person of ordinary skill in the art tempted to combine Fixel and Persson as postulated by the examiner would never modify Fixel's device such that the leaf springs could move laterally and rotationally within the cavity as claimed, especially since Persson acknowledges the problems associated with wear particle generation from the implant.

Hence, claim 1 is non-obvious over Fixel, in combination with Persson or any other document. Accordingly, the claims that depend from claim 1 are likewise deemed non-obvious for at least the same reasons.

The examiner singled out claims 14-17 as unpatentable over Fixel in view of Persson. As a basis for this rejection, the Examiner has asserted that the Fig 2 embodiment of Fixel shows that the "first and second components are pivotable around a plurality of axes, including perpendicular axes."

In response, Applicant asserts that this is not a correct interpretation of the Fixel Fig. 2 embodiment. Fixel explains at column 3, line 55-62 that the Fig. 2 embodiment is the same internally as the Fig. 1 embodiment, and the same spring stack 17 is merely enclosed within a pair of hemispherical members 20, 21. The same design of stacked leaf springs can be seen in dotted lines inside the enclosure of the hemispherical members 20, 21. At the end of this

passage, Fixel makes clear that the hemispherical members 20, 21 allow the same range of movement of the support members 11, 12 that extend into the fingers as the Fig. 1 embodiment. There is no disclosure of any other range of movement. Accordingly, the rejection of claims 14 – 17 on this basis does not appear to be justified, and is therefore traversed on this basis.

Claims 14-17 are of course also allowable for other reasons because they are all dependent ultimately on claim 1, which is allowable over a combination of Fixel and Persson as argued above.

Withdrawal of the rejection of claims 1-5, 8-12, 14-22, 31, 34 and 35 is requested.

35 USC § 103 rejection of claims 6 and 7

The Examiner rejected claims 6 and 7 as unpatentable over Fixel and Persson in view of Vitale (US 5,683,466). Claim 7 is cancelled, and the rejection is therefore deemed moot in so far as it relates to claim 7.

Claim 6 depends from claim 1, and quite apart from its own merits is deemed to be allowable for the same reasons claim 1 is allowable over Fixel and Persson. Vitale does not supply the elements of claim 1 missing from Fixel and Persson.

Withdrawal of the rejection of claim 6 is requested.

35 USC § 103 rejection of claims 24 – 29

The Examiner rejected claims 24-29 as unpatentable over Fixel and Persson in view of Huebner (US 5,702,472). Claim 27 is cancelled, and the rejection is deemed moot in so far as it relates to claim 27.

Claims 24 – 26, 28, and 29 depend from claim 1, and quite apart from their own merits are deemed to be allowable for the same reasons claim 1 is allowable over Fixel and Persson. Huebner does not supply the elements of claim 1 missing from Fixel and Persson.

Withdrawal of the rejection of claims 24 – 26, 28, and 29 is requested.

Allowability of claim 13

Applicants note with appreciation that claim 13 has not been rejected or objected to by the examiner. Applicants therefore regard the lack of rejection or objection as an indication of the allowability of the subject matter of claim 13.

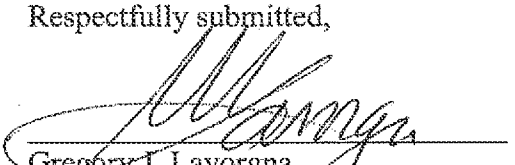
Claim 13 has been amended to incorporate its base claim and any intervening claims. Claim 13 as amended is therefore deemed allowable.

CONCLUSION

For the foregoing reasons, Applicants believe that the application is in condition for allowance, and and early notice of allowance is earnestly solicited.

Should the Examiner have any questions or comments regarding Applicants' amendments or response, he is asked to contact Applicants' undersigned representative at (215) 988-3309. Please direct all correspondence to the below-listed address. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted,



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